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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,013	04/26/2000	Toshiro Ono	L0461/7086(JRV)	1882
7590 John R Van Amsterdam c/o Wolf Greenfield and Sacks P C Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			EXAMINER CANELLA, KAREN A	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			04/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/559,013	<b>Applicant(s)</b> ONO ET AL	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 54, 56, 60, 62, 64, 66, 76, 133 and 137 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 54, 56, 60, 62, 64, 66 and 133 is/are allowed.
- 6) ☐ Claim(s) 76 is/are rejected.
- 7) ☐ Claim(s) 137 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### DETAILED ACTION

Claims 56 and 76 have been amended. Claims 54, 56, 60, 62, 64, 66, 76, 133 and 137 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/168,353, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application does not provide a written description for SEQ ID NO:23. Accordingly the effective priority date will be the filing date of the 09/559013, April 26, 2000.

The rejection of claim 76 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit comprising isolated nucleic acid sequence consisting of SEQ ID NO:27 and SEQ ID NO:28, does not reasonably provide enablement for a kit comprising a pair of isolated nucleic acids which consist essentially of 12-32 contiguous nucleotides of SEQ ID NO:23, nucleic acid molecules which differ from that of (a) due to codon degeneracy, and (c) complements of (a) or (b), wherein the pairs of isolated nucleic acid molecules do not overlap. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The instant claims are drawn to primer pairs. In order for said pair of primers to function in polymerase chain reaction, one member of the pair must be from the sense strand and the other member must be from the anti-sense strand. In the instant case, the claim allows for both primers to be from the sense strand or both primers to be from the anti-sense strand. The specification has not taught a use for such a primer pair outside of the scope of PCR (page 19, line 26). The specification contemplates that an individual "unique" fragment can be used to generate fusion proteins for generating antibodies (page 19, lines 26-28). However, not all of the fragments encompassed by the primer pairs of the instant claim would be expected to make a useful antibody due to the requirement that the antibody epitope be accessible to interaction with an antibody molecule. Epitopes which are not accessible due to the three-dimensional configuration of the protein, or the presence of proteins which mask an intracellular epitope would not be expected to provide an antibody which can be used to detect the protein encoded by SEQ ID NO:23. Further, the claims include fragments of SEQ ID NO:23 without regard to the reading frame of SEQ ID NO:23 or the sense or anti-sense strand of SEQ ID NO:23, therefore a large number of the fragments encompassed by the claim would not encode a fragment of the protein encoded by SEQ ID NO:2.

With respect to primers for PCR, Ashlock et al (Proceedings of the IEE Symposium on Computational Intelligence in Bioinformatics and Computational Biology, 2004, pp. 190-197) that out of a collection of 27408 hypothetical "correct" primer pairs 17224 amplify correctly while 10184 fail to amplify at all or amplify multiple targets (page 191, second column, lines 10-13). Thus, it cannot be expected that all of the primers encompassed by this claim will be useful for the polymerase chain reaction and one of skill in the art would be subjected to undue experimentation in order to use the broadly claimed primer pairs.

Applicant has amended the claim to specify that the other member of the pair of isolated nucleic acid molecules consists essentially of a complement of (a) or (b) wherein the pair does not overlap each other. This amendment fails to provide a pair of nucleic acids which will function in an amplification reaction because primer pairs which are complementary will dimerize with each other rather than with the target sequence. Also it would be impossible to

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have a pair of primers which were essentially complementary , but not overlapping as required by the claim.

Claim 137 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicant's amendments and arguments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

4/1/2007

  
KAREN A. CANELLA, Ph.D.  
PRIMARY EXAMINER